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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/049,666

02/15/2002

Tsuneji Suzuki

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

10/29/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/049,666	Applicant(s) SUZUKI ET AL.	
	Examiner GOLLAMUDI S. KISHORE	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-4-10.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44 and 46-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44 and 46-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The RCE dated 10-4-10 is acknowledged.

Claims included in the prosecution are 44, 46 and 48.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 44 and 46-48 are rejected under 35 U.S.C. 103 (a) as being unpatentable over EP 0847 992 by itself or in combination with Savastano (5,681,584), further in view of Dietrich (7,041,313), Okayama (5,665,348), Ueda (5,962,454) individually or in combination.

According to instant claims, the formulation of the benzamide derivative contain

- 1) An excipient which is ***D-mannitol***
- 2) A lubricant which is ***magnesium stearate***
- 3) A disintegrant which is ***carboxy methyl starch sodium***
- 4) At least one member selected from the group consisting of an amino compound and inorganic base: The inorganic base is sodium carbonate.***

Claim 46 in addition recites ***polyethylene glycol***.

EP teaches benzamide derivatives claimed by applicant (pages 5-44).
Additionally, EP teaches that the active ingredient may be used in general pharmaceutical compositions, and may be prepared with generally used diluents or excipients, such as binders, extenders, fillers, moisturizers, disintegrants, surfactants,

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and lubricants. EP also teaches that the pharmaceutical dosage form can be a tablet, pill, powder, solution, suspension, emulsion, granules, capsule, injection or suppository. More specifically, EP teaches the use of lactose, calcium carbonate, amino acids, starch, methyl celluloses, calcium Carmellose, sugars, stearates, talc, polyethylene glycol, sodium alginate and many other well known excipients (page 46, lines 5- 39). The selection of appropriate excipients in combination with claimed benzamide derivative would have been obvious to one of ordinary skill in the art with a reasonable expectation of success, since EP is suggestive of these art known excipients together with the benzamide derivative. The examiner also points out that in tablets routinely contain, binders, disintegrants, lubricants and buffering substances such as carbonates and bicarbonates and choosing the appropriate compounds falling under each category with a reasonable expectation of success would have been obvious to one of ordinary skill in the art at the time the invention was made.

EP does not specifically teach mannitol, carboxymethyl starch and sodium carbonate.

Savastano while disclosing tablet formulations of Benzamide derivatives suggests that excipients such as mannitol, magnesium carbonate, binders such as carboxymethylcellulose be used. Savastano further teaches that suitable tablet lubricants include calcium stearate (col. 7, line 4 through col. 8, line 65).

Dietrich teaches the equivalency between sodium carboxymethylcellulose and sodium carboxymethyl starch taught by Savastano and starch and alginates taught by EP in tablet preparations (col. 2, lines 41-53. Dietrich further teaches the used of

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auxiliaries such as calcium stearates and mannitol as preferred filler (col. 2, lines 54-61).

Okayama similarly teaches the equivalency between carboxymethylcellulose and carboxymethylstarch and also the equivalency between sugars such as lactose and mannitol and magnesium stearate and calcium stearate taught by Savastano. Okayama also teaches polyethylene glycol (col. 3, line 67 through col. 4, line 16).

Ueda similarly teaches the equivalency between carboxymethylcellulose and sodium carboxymethyl starch. Ueda also teaches the equivalency between calcium carbonate and sodium carbonate (col. 7, lines 10-29).

The use of mannitol, carboxymethyl starch, magnesium stearate and sodium carbonate in the compositions of EP would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since the reference of Savastano is suggestive of the use of these excipients with other benzamide derivatives. Although Savastano does not teach magnesium salt of stearic acid or the use of sodium carbonate instead of magnesium carbonate, one of ordinary skill in the art would use any metal as the cationic part in these salts with the expectation of obtaining similar results and also because of the equivalency between magnesium stearate and calcium stearate taught by Okayama and the equivalency between calcium and sodium carbonates taught by Ueda. Although Savastano does not teach the use of carboxymethyl starch, one of ordinary skill in the art would be motivated to use this compound instead of carboxymethylcellulose because of the equivalency between these compounds as taught by Okayama and Ueda. As pointed out before, adjusting

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the pH of the composition with acids and bases to obtain the desired pH at which the benzamide derivatives are fully active without degradation is well within the skill of the art. Furthermore, as pointed out before, tablets routinely contain, binders, disintegrants, lubricants and buffering substances such as carbonates and bicarbonates and choosing the appropriate compounds falling under each category with a reasonable expectation of success would have been obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GOLLAMUDI S. KISHORE whose telephone number is (571)272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK